UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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| IRIS MARKEWICH, Derivatively, On behalf of MEDTRONIC, INC,<br><br>Plaintiff,<br><br>v.<br><br>ARTHUR D. COLLINS, JR., WILLIAM A. HAWKINS, RICHARD H. ANDERSON, DAVID L. CALHOUN, DENISE M. O'LEARY, KENDALL J. POWELL, ROBERT C. POZEN, JACK W. SCHULER, MICHAEL DEMANE, STEPHEN MAHLE, PAT MACKIN, SUSAN ALPERT, STEPHEN OESTERLE, GARY ELLIS,<br><br>Defendants,<br><br>-and-<br><br>MEDTRONIC, INC.,<br><br>Nominal Defendant. | Civil Action No. _____<br><br>**DERIVATIVE COMPLAINT**<br><br>**Jury Trial Demanded** |

Plaintiff Iris Markewich, by her attorneys, alleges upon personal knowledge as to her own acts and upon information and belief as to all other matters, based upon the investigation conducted by counsel which included, *inter alia*, a review of Securities and Exchange Commission ("SEC") filings, news reports, analyst reports, press releases, and other publicly available documents, as follows:

## NATURE OF THE ACTION

1. This action is brought derivatively on behalf of nominal defendant Medtronic, Inc. Inc. ("Medtronic" or the "Company") against certain directors and officers of Medtronic for failing to properly oversee and/or implement policies, procedures, and rules to ensure that the Company's Sprint Fidelis® Defibrillator Leads could be safely used by patients and for the failure to take corrective and curative steps to remedy problems with the Fidelis Leads even though defendants knew that the devices were suffering from a material number of serious fractures and failures that necessitated a product recall.

2. The relevant time period herein is from November 20, 2006 through present (the "Relevant Time Period").

3. Medtronic is a global medical technology company, doing business in more than 120 countries, and a leading manufacturer of implantable biomedical devices.

4. Medtronic researched, developed, manufactured and marketed small diameter, high voltage, implantable cardioverter-defibrillator (ICD) leads under the trade name Sprint Fidelis® Defibrillator Leads ("Fidelis Leads"). As reported in an October 30, 2007 Wall Street Journal article, as of early 2007 "about 90% of new Medtronic defibrillators used Fidelis [L]eads [and] some 268,000 of the devices have been implanted in people around the world …."

5. Fidelis Leads were approved by the U.S. Food and Drug Administration ("FDA") in September 2004. Shortly after the Fidelis Leads were introduced to the market, however, defendants knew and/or recklessly disregarded facts demonstrating that a statistically significant percentage of the Leads suffered from potentially fatal defects. In the period from September 2004 to January 2007 alone, 679 adverse event reports regarding the Fidelis Leads were submitted to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. Neither the existence nor the contents of these reports were disclosed to investors or patients in

Medtronic's public filings including the Company's Form 10-Qs, Form 10-Ks, and various press releases.

6. During this same period of time, physicians from the Minneapolis Heart Institute independently observed a higher rate of Fidelis Lead failures than expected and, as a consequence, conducted their own study, which was reported in the Heart Rhythm Journal.[1]

7. This study compared the actuarial survival of Fidelis Leads model 6949, implanted in 583 patients at the Minnesota Heart Institute between September 2004 and February 2007, against Sprint Quattro Secure ("Sprint Quattro") leads model 6947, implanted in 285 patients at the Minnesota Heart Institute between November 2001 and March 2007, and found the difference in survival to be significant: the failure rates for the Fidelis Lead model 6949 and Sprint Quattro model 6947 "were 0.01/patient-year and 0.001/patient-year, respectively."

8. An analysis also was compiled of adverse event reports[2] regarding the Fidelis Leads on the MAUDE database. The physicians found that between September 2004 and July 2006 Medtronic analyzed 125 Fidelis Leads returned to the Company and determined that 77, or 62%, were defective. None of the 357 adverse event reports submitted by Medtronic "after July 2006 contained the results of a returned lead analysis."

9. In an addendum, the physicians noted between February 10, 2007, the date of their original search of the MAUDE database locating 679 adverse event reports, and April 15, 2007, that there were 195 new adverse event reports on the MAUDE database regarding the

[1] Robert G. Hauser, MD, Linda M. Kallinen, BS, Adrian K. Almquist, MD, Charles C. Gornick, MD, William T. Katsiyiannis, MD, *Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead ("Early Failure")*, Heart Rhythm Journal, Jul. 2007 (vol. 4, issue 7) at 892-96.

[2] "The FDA requires manufactures to report adverse events that are communicated to them verbally or in writing, and they must report the results of investigations into the causes of device malfunctions." *Id.* at 893.

Fidelis Leads. Of the 195 reports, 101 contained results of a returned lead analysis by Medtronic that found 75 of the Fidelis Leads, or 74%, were defective.

10. The physicians' study determined the Fidelis Lead model 6949 "is prone to early failure," and "significantly less reliable" than the Sprint Quattro model 6947, and advised that they would no longer use the Fidelis Leads in their practice. Finally, they concluded that use of the Fidelis Leads should "*be limited until the failure mechanism is understood and corrected.*" (Emphasis added.)

11. Early copies of the physicians' study were shared with Medtronic's management, as well as with FDA. Defendants, however, had little interest in any type of moratorium with respect to the use of the Fidelis Leads.

12. Defendants were similarly unwilling to disclose that any problem existed with the Fidelis Leads that were being used in 90% of the Company's new defibrillators, and reluctant to surrender gains obtained in Medtronic common stock price and competitive market share. Just months before, in November 2006, Medtronic saw its share price surge more that 9.2% after releasing news regarding the Company's fiscal second quarter results that exceeded Wall Street expectations.

13. A November 21, 2006 article from AFX International Focus titled *Medtronic Rises on 2Q Results, Upgrade*, in relevant part, reported the following:

> Shares of Medtronic Inc. jumped Tuesday after the world's largest medical device maker's fiscal second quarter results exceeded Wall Street expectations late Monday, resulting in an upgrade by at least one analyst.
>
> Medtronic shares surged $4.52, or 9.2%, to 53.57 in afternoon trading on the New York Stock Exchange at more than triple their average volume. …
>
> JPMorgan analyst Michael Weinstein upgraded Medtronic to 'Overweight' from 'Neutral' *on the belief that the U.S. implantable*

> *defibrillator, or ICD, market has already bottomed out and that a rise in sales over the past quarter signals a turnaround.*
>
> …
>
> Medtronic reported second-quarter ICD revenue of $764 million, up 4 percent from last year. Sales of the devices were up 14 percent from the first quarter of 2006 and the company claimed 56 percent of the worldwide ICD market.
>
> *Software glitches and battery problems in implanted devices across the sector have raised anxiety over ICDs and pacemakers, resulting in a softness in recent sales. Medtronic recently launched a $100 million campaign to raise public awareness of pacemakers and ICDs, after the market was hit by a rash of industry wide safety alerts mostly from Guidant Corp., now a part of Boston Scientific.* (Emphasis added.)

14. On November 22, 2006, an article in Business Week Online titled *Medtronic: Investors Take Heart*, similarly reported, in relevant part, the following:

> Medtronic, Inc. (MDT) share prices surged 9.4% on Nov. 21, *as Wall Street cheered that the market for heart monitoring devices might have stopped missing beats.*
>
> The Minneapolis company, which makes medical instruments such as cardiac stents and insulin pumps, said late Nov. 20 that it earned more money from the sale of implantable cardioverter defibrillators (ICDs), which are electronic devices used for monitoring the heart and the company's largest product line.
>
> As Medtronic grabbed market share from rivals in the business, its ICD-related revenue grew to $764 million, up 14% compared to the previous quarter and 4% compared to the prior year's quarter. *Medtronic says it now holds an estimated 56% of the worldwide ICD market and more than 50% of the worldwide pacemaker market.*
>
> Medtronic's total revenue rose 11% year over year to $3.075 billion during the recent quarter. (Emphasis added.)

15. On March 21, 2007, Medtronic delivered a "Dear Doctor" letter to selected physicians regarding its receipt of "reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers"

with the Fidelis Leads. The letter explained, however, that the Company's own investigation "suggests that variables within the implant procedure may contribute significantly to these fractures." In other words, the "higher than expected conductor fracture rates" were the implanting physician's fault not a problem with the lead. Defendants, however, did not publish this letter publicly or send it to FDA even though the issues raised therein were substantial and concerned the very issue reported by the Company to FDA in adverse event reports, i.e. fractures of the Fidelis Leads.

16. Even after Medtronic's "Dear Doctor" letter in March 2007, evidence of problems with the Fidelis Leads continued to mount. Rather than disclose to investors, patients and physicians the growing reluctance by physicians across the country to use the Fidelis Leads in their practice, Medtronic presented a contrary outlook. In its Form 10-K for the fiscal year ended April 27, 2007, filed with the SEC on June 25, 2007, Medtronic provided positive information about the Fidelis Leads:

> The strong market acceptance of [the Fidelis Leads] reflects CRDM's[3] continued product innovation as well as an overall expansion of the tachyarrhythmia and heart failure markets due to increasing clinical data that supports the uses of these devices for certain patient populations.

17. Between July and September 2007, Defendants continued to receive evidence of problems with the Fidelis Leads. According to the October 30, 2007 Wall Street article:

> The company was trying to get to the bottom of what was becoming a crisis. Medtronic says it learned about the five deaths potentially linked to Fidelis leads between August 2006 and this

[3] "CRDM" is the Medtronic acronym for Cardiac Rhythm Disease Management. CRDM is Medtronic largest business segment and described in the Form 10-K as "the world's leading supplier of medical devices for cardiac rhythm disease management." CDRM products "primarily consist of pacemakers, implantable defibrillators, leads, ablation products, electrophysiology catheters, and information systems for the management of patients with [Medtronic] devices."

> September. The patient study it had begun in 2004 by late July had data on 654 patients, and the separate, eight-month CareLink analysis of 25,000 patients was well under way. Using that information, Medtronic analysts by October determined that the Fidelis overall failure rate -- 2.3% over 30 months on the market -- was higher than the 0.9% rate for one of its Quattro models.

18. On October 15, 2007, Medtronic issued another "Dear Doctor" letter disclosing that the Company was suspending the distribution of the faulty leads and that physicians should cease implanting them immediately:

> Dear Doctor,
>
> This letter provides important information on Sprint Fidelis lead performance and recommendations for ongoing patient management. Our records indicate that you have implanted or are following patients with Sprint Fidelis leads (Models 6930, 6931, 6948, 6949). In consultation with our Independent Physician Quality Panel, we are voluntarily suspending distribution of Sprint Fidelis leads worldwide. This decision is based on a variety of factors detailed in this letter that when viewed together, indicate that suspension of implantation is the appropriate action. You should no longer implant Sprint Fidelis leads, and you should return any unused product to Medtronic.
>
> Background
>
> As we reported in March 2007, there are two primary locations[] where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. The potential for defibrillation lead fracture to result in or contribute to inappropriate therapies or death has been previously reported.[] As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide. Based on current information, we have identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. We have confirmed 665

> chronic fractures in returned leads. Approximately 90% of these fractures have occurred in the anode or cathode conductors, while 10% have occurred in the high voltage conductors.
>
> Performance Update
> Since our March 21st communication, we have examined six months additional Returned Product Analysis (RPA) and Medtronic System Longevity Study (SLS) data. In addition, we have performed extensive analysis using the Medtronic CareLink® Network (25,000 devices) …. These data give us confidence in our current understanding of Sprint Fidelis' performance.
>
> …
>
> Additional Communication
> The HRS-recommended Physician Device Advisory Notice for this communication is attached. The information in this letter will be posted on Medtronic.com on October 15th. Consistent with the HRS[] recommendations on device advisory communications we will be informing patients with affected devices, advising them to contact you for more information. The patient letter will be sent on October 22nd.
>
> We are notifying regulatory agencies of this communication. We will continue to provide performance updates every six months via our Product Performance Report.
>
> Nothing is more important to Medtronic than patient safety. …[4] (Emphasis added.)

19. On October 15, 2007, the FDA issued a Class 1 recall for Medtronic's Fidelis Leads.[5]

[4] *Urgent Medical Device Information Sprint Fidelis® Lead Patient Management Recommendations*, (Oct. 15, 2007) <http://www.medtronic.com/fidelis/physician-letter.html>.
[5] *Class 1 Recall: Medtronic Inc. Sprint Fidelis® Defibrillator Leads*, (last modified Oct. 17, 2007) <http://www.fda.gov/cdrh/recalls/recall-101507.html>.

## THE PARTIES

**Plaintiff**

20. Plaintiff, Iris Markewich, is, and at all relevant times, was the owner of shares of Medtronic Stock. Plaintiff resides in New York, New York.

**Nominal Defendant**

21. Nominal defendant Medtronic, Inc. is a Minnesota corporation with its principal executive offices located in Minneapolis, Minnesota.

**Defendants**

22. The following defendants were either a member of Medtronic's Board of Directors and/or senior management team during the Relevant Time Period.

23. Defendant Arthur D. Collins, Jr. (Collins") is a director of the Medtronic and has served as Chairman of the Board since April 2002. Collins served as the Company's Chief Executive Officer from April 2002 through August 23, 2004, President and Chief Executive Officer from May 2001 to April 2002, President and Chief Operating Officer from August 1996 to April 2001, Chief Operating Officer from January 1994 to August 1996 and Executive Vice President of Medtronic and President of Medtronic International from June 1992 to January 1994. Collins has served as a member of Medtronic's Board of Directors since 1994. During the Relevant Time Period, Collins participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and the Company's shareholders. For Medtronic's fiscal year 2007, Collins received $11.5 million in executive compensation from Medtronic. Additionally, upon information and belief, during the Relevant Time Period, Collins sold 547,292 shares of Medtronic Stock for in excess of $27 million. Given his substantial oversight and leadership responsibilities, he breached his fiduciary

duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given the existence of information to the contrary.

24. Defendant William A. Hawkins ("Hawkins") was named President and Chief Executive Officer on August 23, 2007. He served as the Company's President and Chief Operating Officer from May 2004 until August 2007, and as Senior Vice President and President, Medtronic Vascular, from January 2002 to May 2004. Hawkins has served as a member of Medtronic's Board of Directors since March 2007. During the Relevant Time Period, Hawkins participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and the Company's shareholders. For Medtronic's fiscal year 2007, Hawkins received $4.4 million in executive compensation from Medtronic. Additionally, upon information and belief, during the Relevant Time Period, Hawkins sold almost 3,916 shares of Medtronic Stock for in excess of $206,300. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that evidence existed, known to management, that the Fidelis Leads were dangerous.

25. Defendant Richard H. Anderson ("Anderson") has served as a member of Medtronic's Board of Directors since 2002. Anderson is the current Chairperson of the Company's Compensation Committee and a member of the Corporate Governance Committee

and Nominating Subcommittee. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

26. Defendant David C. Calhoun ("Calhoun") has served as a member of Medtronic's Board of Directors since 2007. Calhoun is also a member of the Audit, Corporate Governance and Technology and Quality Committees. During the Relevant Time Period, Calhoun participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

27. Defendant Denise M. O'Leary ("O'Leary") has served as a member of Medtronic's Board of Directors since 2000. O'Leary is the current Chairperson of the Company's Audit Committee and a member of the Corporate Governance Committee and Nominating Subcommittee. During the Relevant Time Period, O'Leary participated in the issuance of improper statements, including the preparation of the improper press releases and

SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Given her substantial oversight and leadership responsibilities, she breached his fiduciary duties to the Company through her failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads though defendants were in possession of contrary information.

28. Defendant Kendall J. Powell ("Powell") has served as a member of Medtronic's Board of Directors since 2007. Powell is also a member of the Compensation, Corporate Governance and Technology and Quality Committees. During the Relevant Time Period, Powell participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

29. Defendant Robert C. Pozen ("Pozen") has served as a member of Medtronic's Board of Directors since 2004. Pozen is also a member of the Audit, Corporate Governance and Technology and Quality Committees. During the Relevant Time Period, Pozen participated in the issuance of improper statements, including the preparation of the improper

press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

30. Defendant Jack W. Schuler ("Schuler") has served as a member of Medtronic's Board of Directors since 1990. Shuler is also a member of the Compensation and Corporate Governance Committees and Nominating Subcommittee. During the Relevant Time Period, Shuler participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Given his substantial oversight and leadership responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

31. Defendants Collins, Hawkins, Anderson, Calhoun, O'Leary, Powell, Pozen, , and Shuler are sometimes collectively referred to as the ("Director Defendants" )

32. Michael Demane ("Demane") is the Company's Chief Operating Officer having been elected on August 23, 2007. Previously, he served as Senior Vice President and President

Europe, Canada, Latin America and Emerging Markets from August 2005 directing the Company's operations in those regions. As Chief Operating Officer, he breached fiduciary duties he owed to the Company to ensure that the Fidelis Leads were safe and that the Company and other members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

33. Stephen H. Mahle ("Mahle") assumed the newly created position of Executive Vice President and Senior Healthcare Policy Advisor in August 2007. According to the Company's website, "[i]n this role, Steve works to develop industry and professional policies that advance patient care and address changes in the U.S. healthcare environment." Accordingly, given his role as an advocate for patients and best practices, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and other members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

34. Pat Mackin ("Mackin") was named Senior Vice President and President, Cardiac Rhythm Disease Management in August 2007. According to the Company's website, "he is responsible for the overall strategic direction for CRDM and its day-to-day operations. He joined Medtronic CRDM in November 2006 as Vice President, CRDM Commercial Operations. In this role, he was responsible for the day-to-day activities of CRDM research, product development, quality, operations, sales and marketing." Accordingly, given his direct responsibilities in the CRDM quality area, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that

Company and other members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

35. Susan Alpert, Ph.D., M.D. ("Alpert") was named Senior Vice President - Chief Quality and Regulatory Officer in 2005. According to the Company's website, "she is responsible for all Medtronic quality, regulatory and clinical compliance efforts including overseeing health policy and payment." Accordingly, given her compliance and regulatory oversight responsibilities, she breached her fiduciary duties to the Company through her failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and other members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

36. Stephen N. Oesterle, M.D., ("Oesterle") joined the company in 2002, after serving as Associate Professor of Medicine at the Harvard University Medical School and Director of Invasive Cardiology Services at Massachusetts General Hospital, Boston. According to the Company's website, "[i]n his position as Senior Vice President for Medicine and Technology, Oesterle provides executive leadership for Medtronic scientific research, formation of technological strategies and continued development of strong cooperative relationships with the world's medical communities." Given his clinical training and experience, coupled with his strategic responsibilities, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and other members of management did not issue false statement to patients and the

markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

37. Gary Ellis ("Ellis") was named Sr. Vice President and Chief Financial Officer effective May 1, 2005. According to the Company's website, "he is responsible for the following functions: treasury, tax controllership, internal audit, and investor relations. Shortly after being named CFO, Gary was made responsible for Global Business Solutions (which includes quality, supply chain, facilities, etc.) at Medtronic. Given his financial reporting and quality oversight duties, he breached his fiduciary duties to the Company through his failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and other members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

38. Defendants Demane, Mahle, Mackin, Alpert, Oesterle, and Ellis are sometimes collectively referred to as the ("Management Defendants").

39. The Director Defendants and the Management Defendants, where appropriate, are sometimes referred to collectively as the "Defendants".

40. Defendants are jointly and severally liable for damages as demanded herein.

41. By reason of their positions at Medtronic, each of the Defendants named in this Complaint had access to internal Company documents, reports and other information, including adverse non-public information about its business, financial condition and future prospects, and attended management and/or board of directors meetings. As a result, they were responsible for the truthfulness and accuracy of the Company's public reports, statements and releases.

42. By virtue of their high-level positions at Medtronic, each of the Defendants directly participated in the management and/or oversight of the Company and was privy to confidential, proprietary information about the Company's business operations. They were involved or participated in drafting, producing, reviewing, approving and/or disseminating the false and misleading statements alleged in this Complaint regarding the safety and efficacy of the Company's Fidelis Leads and were thus aware that the statements were being made, and approved and ratified them.

43. Given each Defendants' substantial oversight and leadership responsibilities, he/she breached fiduciary duties to the Company through the failure to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that ample information existed demonstrating the contrary.

**Relevant Non-Parties**

44. Shirley Ann Jackson ("Jackson") has served as a member of Medtronic's Board of Directors since 2002. Jackson is the current Chairperson of the Company's Technology and Quality Committee and a member of the Audit and Corporate Governance Committees. During the Relevant Time Period, Jackson participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Demand on Jackson would be a futile endeavor because she failed to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets

that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

45. James T. Lenehan ("Lenehan") has served as a member of Medtronic's Board of Directors since 2007. Lenehan is also a member of the Compensation, Corporate Governance and Technology and Quality Committees. During the Relevant Time Period, Lenehan participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Demand on Lenehan would be futile because he failed to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

46. Jean-Pierre Rosso ("Rosso") has served as a member of Medtronic's Board of Directors since 1998. Rosso is the current Chairperson of the Company's Corporate. Governance Committee and Nominating Subcommittee, and a member of the Audit Committee. During the Relevant Time Period, Rosso participated in the issuance of improper statements, including the preparation of the improper press releases and SEC filings, and was quoted in and approved the issuance of the Company's false and misleading made to the press, securities analysts and Medtronic's shareholders. Demand would be futile on Rosso he failed to sufficiently oversee safety and efficacy issues associated with Fidelis Leads and to ensure that Company and members of management did not issue false statement to patients and the markets

that supported the safety and efficacy of the Fidelis Leads given that defendants and management were privy to information to the contrary.

## JURISDICTION AND VENUE

47. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a) because the derivative plaintiffs and defendants are citizens of different states and the matter in controversy exceeds $75,000. This action is not a collusive action designed to confer jurisdiction on a Court of the United States that it would not otherwise have. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a).

48. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and 1391(b) because nominal defendant Medtronic is headquartered in this District, and a substantial portion of the transactions and wrongs complained of herein occurred in this District.

49. Additionally, there are several suits already pending in this District in which Medtronic and some or most of the individual defendants in this action are named as defendants, and, thus, discovery and pretrial proceedings can be coordinated in this District.

## SUBSTANTIVE ALLEGATIONS

50. Medtronic, its management and Board of Directors are not strangers to regulatory scrutiny, sanction, and liability. Indeed, the Company's recent past is marked with product related safety problems, fines, and events that have had adverse effects on the Company's reputation.

51. For example, in February 2005, Medtronic began to voluntarily advise physicians about a potential battery shorting problem in its various Marquis-brand ICDs. The Company provided physicians with a list of potentially affected patients and recommended that physicians communicate with those patients so they could manage the potential issue in a manner they felt

was appropriate for their individual patients. Subsequent to this voluntary field action, later classified by the FDA as a Class II Recall, a number of lawsuits were filed against Medtronic in various state and federal jurisdictions. On December 21, 2007, the Wall Street Journal reported that the Company agreed to pay $114 million to settle the lawsuits related to its Marquis line of ICDs.

52. In December 2006, Medtronic announced that it was spinning off its external defibrillator business into a new business called Physio-Control Inc. ("Physio"), purportedly to focus on its "higher-growth treatments for chronic conditions such as heart disease and diabetes." Not a month later, Physio suspended U.S. shipments of external defibrillators and other products. As reported in a January 17, 2007 article in Minneapolis/St. Paul Business Journal entitled *Medtronic Suspends Shipments of Physio-Control Products*, "[c]ompany officials said they're not recalling any products, but need to 'address quality system issues' identified by the company, its parent Medtronic (NYSE: MDT) and the U.S. Food and Drug Administration." The Seattle Times reported the same day that the "halting of product shipments means Medtronic will delay the spinoff of Physio-Control as an independent public company …."

53. In July 2006, the Company paid a $40 million fine to settle to settle two U.S. Justice Department suits regarding improper compensation and sales tactics for surgeons. According to the allegations, the Company paid kickbacks that also included sham royalty and consulting agreements between 1998 and 2003 to doctors.

54. These problems, among others, placed the Defendants on notice that the Company was subject to regulatory scrutiny from a number of fronts and that its products had been the subject of quality control issues and fines, exposing Medtronic to large litigation liabilities and reputational harm.

55. Given this history of malfeasance, the Defendants should have undertaken an active and aggressive role in connection with *all* quality control issues and *particularly* those arising out of the Fidelis Leads especially after it became obvious that there was a substantial problem with the product.

56. Indeed, the members of the board and the Director Defendants should have actively overseen the process associated with the issuance of the March 21, 2007 "Dear Doctor" letter that failed to properly inform patients, physicians, and stockholders about the known risks associated with the Fidelis Leads. Significantly, members of management and the board knew as of at least February 2007, based upon reports delivered to them by Robert G. Hauser, M.D., a respected member of the medical community in Minnesota, that Fidelis Leads were prone to malfunction. Dr. Hauser explained to Defendants and the Company that the malfunctions were not the result of poor implantation or technique by physicians, as the Company's March, 2007 "Dear Doctor" letter represented, but caused by problems inherent to the Fidelis Leads unrelated to practitioner insertion.

**The Fidelis Leads, the Myriad Problems**
**and the Minneapolis Heart Institute Study**

57. Fidelis Leads were approved by the FDA in September 2004, and shortly thereafter began to evidence problems. In the period from September 2004 to January 2007 alone, 679 adverse event reports regarding the Fidelis Leads were submitted to the FDA's MAUDE database.

58. During this same period, physicians from the Minneapolis Heart Institute independently observed a higher rate than expected of Fidelis Lead failures and, as a

consequence, conducted their own study, which was reported in the Heart Rhythm Journal.[6] A chronology of the events leading to the study was recently reported in an October 30, 2007 Wall Street Journal article titled *Medtronic Recall Exposes Gaps In Medical Safety Spotty Data and Testing Left FDA in the Dark; Firm Cites Five Deaths*. The article provides, in pertinent part, as follows:

> In late January, something unsettling happened at the Minneapolis Heart Institute. On two successive days, patients came to the clinic after their heart defibrillators had jolted them with huge, unnecessary and painful electric shocks. One 65-year-old woman said she'd been zapped 14 times in an hour.
>
> Doctors checked the hospital's records and discovered four similar cases had occurred in recent months. Each stemmed from a broken wire – called a lead – that tells a defibrillator when to send an electric shock to a malfunctioning heart. All six cases involved the Sprint Fidelis 6949, manufactured by Medtronic Inc., a leading medical-device maker.
>
> Within days, the Heart Institute concluded that the Sprint Fidelis wasn't safe enough, told the company of its concerns, and stopped using the product.
>
> Across the country, physicians at leading hospitals from Chicago's Children's Memorial Hospital to Boston's Brigham and Women's Hospital came across similar problems and some took similar steps.
>
> …
>
> Like other leads made by Medtronic and its competitors, the Fidelis leads occasionally broke. But the issue went largely unnoticed until those two patients walked into the Minneapolis Heart Institute's pacemaker and defibrillator clinic, in January.
>
> In both cases, doctors at the clinic determined that the patients' Fidelis leads had fractured and misfired. It worried Linda Kallinen, the clinic's technical director. "We wondered if this was happenstance, or not," she says. Adrian K. Almquist, the doctor

[6] *See* note 1, *supra*.

> who treated the patients, found the cases odd because the fractures had occurred within roughly two years of implant.
>
> Scouring electronic logs of other clinic patients, Ms. Kallinen found reports of four other Fidelis fractures in the previous seven months. She and Dr. Almquist went to Robert G. Hauser, a senior consulting cardiologist at the Heart Institute who has made a career of studying defects in heart devices.
>
> In 2005, Dr. Hauser, 68 years old, was instrumental in triggering the recalls of more than 200,000 defibrillators and pacemakers made by Guidant Corp., now part of Boston Scientific Corp. Eight years ago, he organized other cardiologists to create a private database of failures in defibrillators, pacemakers and leads.
>
> After hearing from Ms. Kallinen and Dr. Almquist, Dr. Hauser combed through his multihospital database. He found similar trends of fractures in that database as well as multiple Sprint Fidelis lead failures in a separate federal database. The Heart Institute decided to stop implanting the Fidelis leads altogether and substitute an older Medtronic lead that appeared to be safer, the Sprint Quattro.
>
> *Dr. Hauser contacted Medtronic. In February, he and several other clinic physicians met at the Heart Institute with Warren Watson, a Medtronic vice president, and an engineer. Dr. Hauser says he told Mr. Watson that Medtronic had a serious problem with its Fidelis lead. Three identical device defects at one hospital, he argues, can signify a broader problem.* (Emphasis added).

59. The study by the physicians compared, *inter alia*, the actuarial survival of Fidelis Leads model 6949, implanted in 583 patients at the Minnesota Heart Institute between September 2004 and February 2007, against Sprint Quattro leads model 6947, implanted in 285 patients at the Minnesota Heart Institute between November 2001 and March 2007. The difference in survival was found to be significant: the failure rate for the Fidelis Lead model 6949 was 10 times greater than the failure rate for the Sprint Quattro model 6947. *See Early Failure*, at 893-94. The physicians further noted that, according to Medtronic, the fracture rate for the Fidelis Lead model 6949 was higher by a multiple of 3 than the fracture rate for the Sprint Quattro model 6947. This difference in fracture rate was equally significant. *Id.* at 894-95.

60. The physicians also compiled an analysis of the 679 adverse event reports on the MAUDE database submitted between September 2004 and January 2007. They found that between September 2004 and July 2006, of the 125 Fidelis Leads returned to the Company, Medtronic determined that 62% were defective. Moreover, none of the 357 adverse event reports on the MAUDE database submitted by Medtronic "after July 2006 contained the results of a returned lead analysis." *Id.* at 894.

61. The physicians determined that the Fidelis Lead model 6949 "is prone to early failure," and "significantly less reliable" than the Sprint Quattro model 6947. In light of these findings, they advised that the Fidelis Lead would no longer be used in the Minneapolis Heart Institute's practice. *Id*.

62. Finally, the physicians concluded that use of the Fidelis Leads should "be limited until the failure mechanism is understood and corrected." *Id.* at 896.

63. According to the October 30, 2007 Wall Street Journal article *Medtronic Recall Exposes Gaps In Medical Safety Spotty Data and Testing Left FDA in the Dark; Firm Cites Five Deaths*, early copies of the study were shared with Medtronic, as well as with the FDA.

64. The study's finding constituted a red flag warning that the Company's product was potentially dangerous and that reputable physicians in the *Company's home town* were unwilling to use it. In fact, those doctors met with the Company in February 2007 and warned management that there was a hazardous defect associated with the Leads. Additionally, by February 2007, the Company had reported to FDA numerous instances of defective Leads and for some unexplained reason elected to stop testing Leads to determine the lack of the defect.

65. Notwithstanding the existence of these clear warnings that a problem was upon them, on March 21, 2007, Medtronic delivered a "Dear Doctor" letter to selected physicians

regarding its receipt of "reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers" with the Fidelis Leads. The letter explained, however, that the Company's own investigation "suggests that *variables within the implant procedure may contribute significantly to these fractures*." (Emphasis added.) In short, the Company discredited the report and blamed the problems on the doctor's insertion techniques. Defendants knew this letter was false.

66. Notwithstanding Medtronic's "Dear Doctor" letter in March 2007, evidence of problems with the Fidelis Leads continued to mount. Increasing numbers of physicians at leading hospitals across the county grew increasing concerned and stopped using the Fidelis Leads in their practices.

**The Truth about the Problems**
**with the Fidelis Leads is Belatedly Disclosed**

67. On October 15, 2007, Medtronic issued a press release announcing the Company's voluntary suspension of distribution of Fidelis Leads. In relevant part, the press release provides:

> Medtronic, Inc. (NYSE:MDT) said today that it has voluntarily suspended worldwide distribution of the Sprint Fidelis® family of defibrillation leads because of the potential for lead fractures. In addition, the company recommends against new implants of the leads (Sprint Fidelis Models: 6930, 6931, 6948, 6949).
>
> The Sprint Fidelis leads are used to deliver therapy in defibrillators only, including Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy – Defibrillators (CRT-Ds). Approximately 268,000 Sprint Fidelis leads have been implanted worldwide. This action does not affect Medtronic pacemaker patients.
>
> The U.S. Food and Drug Administration (FDA) intends to issue a public statement regarding Medtronic's decision at www.fda.gov.
>
> …

> This decision is based on a variety of factors that, when viewed together, indicate that suspending distribution is the appropriate action. Based on Medtronic's extensive performance data, Sprint Fidelis lead viability is trending lower than Medtronic's Sprint Quattro® lead at 30 months (97.7% Sprint Fidelis vs. 99.1% Sprint Quattro). This difference is not statistically significant; however, if the current lead fracture rates remain constant, it will become so over time. Medtronic believes that given this performance trend and its ability to identify the primary fracture locations, this action is in patients' best interest.
>
> Lead fractures may present clinically as audible alerts, inappropriate shocks and/or loss of output. Based on current information regarding the 268,000 implanted leads, Medtronic has identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor.
>
> "There is nothing more important to us than the safety and well-being of patients," said Bill Hawkins, president and chief executive officer of Medtronic. "We take all matters of product quality very seriously and believe this action is the right thing to do given currently available information."
>
> Medtronic Outreach to Physicians and Patients
>
> In conjunction with Medtronic's Independent Physician Quality Panel, Medtronic today communicated, via letter and direct outreach with more than 13,000 physicians worldwide, the Sprint Fidelis lead performance data and updated patient management recommendations for patients who are implanted with Sprint Fidelis leads. These recommendations include device programming and patient management recommendations that will ensure a patient's device is set to more effectively monitor for potential problems and provide an audible alert in the event of lead fractures.

68. On the same day, Medtronic filed the Company's Form 8-K in connection with its earlier press release announcing the Company's voluntary suspension of distribution of Fidelis Leads. In relevant part, the 8-K filing provides the following disclosure:

> Item 7.01. Regulation FD Disclosure.
>
> On October 15, 2007, Medtronic, Inc. announced that it had voluntarily suspended worldwide distribution of the Sprint Fidelis family of defibrillation leads, furnished a press release with the securities and exchange commission on a prior current report on

form 8-K, and hosted an investor webcast. During that webcast and contemporaneously with this filing, Gary L. Ellis, Senior Vice President and Chief Financial Officer of Medtronic, made the following statements:

- In terms of the impact on fiscal second quarter revenues, there are a number of factors to consider. There will likely be significant repercussions on the Japanese market because currently we have no other leads approved in this market.

- In addition, we know that we will have meaningful product returns of the Fidelis lead that we will need to account for as revenue credits in our second quarter. Normally, we would be able to replace these leads with an alternative, but due to the Sprint Quattro supply limitations, we will not be able to resupply the customer's inventory levels until later this fiscal year. It is difficult to estimate the level of Fidelis inventory held by our customers, but it will result in a significant revenue reversal in our second quarter.

- The currently limited Sprint Quattro supply will also have a potentially significant impact on revenue over the final two weeks of our second quarter and the early part of the third quarter. European tenders and customer bulk purchase orders will either have to be adjusted to reflect today's decision or in many cases may not be able to be filled at this time due to the limited Sprint Quattro supply.

- With all of these factors taken together, we currently estimate the revenue impact in the second quarter to be in the range of $150 to $250 million.

- In terms of inventory write offs, we currently estimate an impact of approximately $15 to $20 million in the second quarter. We also anticipate other direct costs associated with this action in the range of $10 to $20 million.

69. On October 15, 2007, the FDA issued a Class 1 recall for Medtronic's Fidelis Leads.

70. Following the disclosure, Medtronic Stock dropped $6.33, more than 11%, to close at $50.00 per share.

71. By letter dated October 16, 2007, Sidney M. Wolfe, M.D., Director, Health Research Group of Public Citizen, and Eunice Yu, Staff Researcher, Health Research Group of Public Citizen, urged the FDA commissioner to conduct an immediate investigation regarding the circumstances underlying the recall of the Fidelis Leads.[7] The Letter sets forth the following:

> Dear Dr. von Eschenbach:
>
> Important live-saving facts seem to have been overlooked intentionally by both the FDA and Medtronic while the two were busy congratulating one another for doing a better job detecting and recalling the Medtronic Sprint Fidelis defibrillator lead than Guidant did in its product recall several years ago.
>
> I urge you to conduct an immediate investigation concerning the following:
>
> 1. The total number of reports of injury associated with the Fidelis lead had climbed to 599 by Jan. 10 2007, including 204 cases in which patients received "inappropriate shocks." (See Table and Figures 1 and 2 below.) The number of injury reports for the first two months of 2007 was 152, compared with 27 reports for the first two months of 2006. Some of this reflects the fact that the longer the defibrillator is implanted, the greater likelihood there is of a fracture, inappropriate shock or other medical problem with the lead. Why did the FDA, aware of the rapidly mounting number of injury reports, not force the company to recall defibrillators not yet implanted in the early part of this year? It is likely that the 1,030 injuries reported to the FDA after Jan. 10 included many patients with defibrillators implanted after this date. Had the recall and further implantations stopped then – instead of nine months later (this week) – many patients would have been spared the injuries and anxiety that occurred with these recent implantations.
>
> Medtronic had been warned about the injuries. Dr. Robert Hauser of the Minneapolis Heart Institute says he contacted Medtronic in early February about the problem and published a review of the injury cases in late March. Indeed, The Heart Institute was so concerned about the risk that it ceased implantation of these

[7] Letter from Sidney M. Wolfe, MD, Director, Health Research Group of Public Citizen, et ano., Andrew C. von Eschenbach, M.D., Commissioner, FDA (Oct. 16, 2007, HRG Publication #1826) <http://www.citizen.org/publications/release.cfm?ID=7547>.

defibrillators in January. (Conversation with Dr. Robert Hauser, October 16, 2007.)

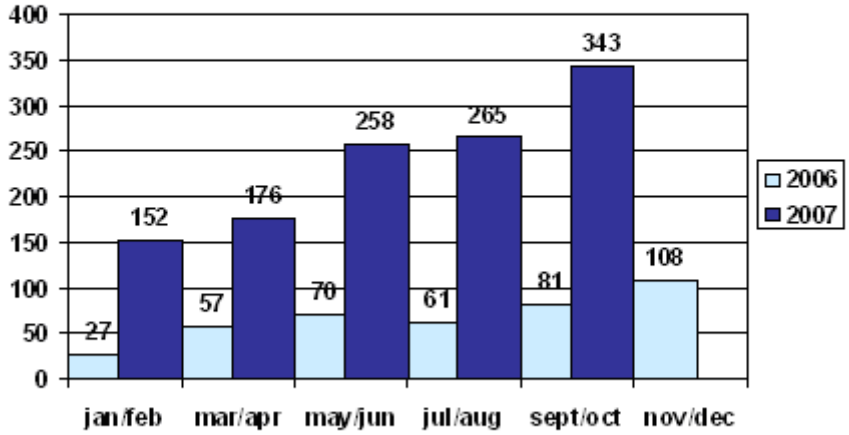
2. As of January, Medtronic and the FDA already were aware of an escalating number of reports of injury in patients with this Fidelis lead. By Jan. 10, the cumulative number of injury reports associated with this lead reported to the FDA database was 599, including 204 cases in which patients got inappropriate electric shocks from their defective defibrillators. (See table below.) Despite this strong warning signal about these defective components, in the same month, January, Medtronic launched a massive direct-to-consumer advertising campaign to lure patients to seek advice from their doctors as to whether they could benefit from having a defibrillator implanted.

Table 1. Fidelis injury reports in FDA files before and after Jan. 10, 2007

| | All injuries | Inappropriate shock |
|---|---|---|
| Jan 10, 2007 and before | 599 | 204 |
| After Jan 10, 2007 | 1030 | 563 |
| TOTAL | 1629 | 767 |

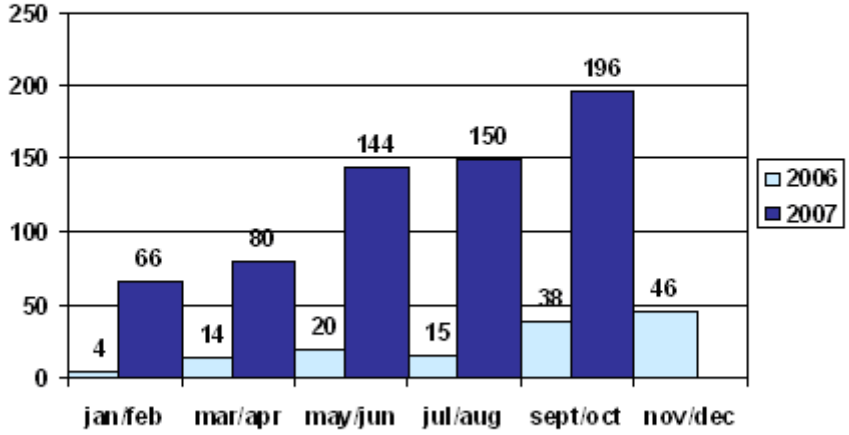
The $100 million Medtronic ad campaign, dubbed “What’s Inside,” including a commercial in which a soft voice promises viewers that inside the device, they’ll find "10,000 more kisses ... 200 more football wins," saying it will "always be there for you – close to your heart with the power to restart it in case of sudden cardiac arrest." The ad was clearly trying to frighten people, including many who would not be candidates for such devices. The goal? Turn that fear into a “let’s not take a chance” mentality that results in more consumers, inadequately informed by the ad, asking their doctors for the devices. Why did the FDA, aware of the rising toll of injuries from Medtronic defibrillators, not stop this advertising campaign?

Figure 1. Reports to the FDA of Injury in Patients With Sprint Fidelis Defibrillator Leads*




Data from FDA Maude Database:10/16/07

Figure 2. Reports to the FDA of Inappropriate Shock in Patients With Sprint Fidelis Defibrillator Leads*




Data from FDA Maude Database:10/16/07

In summary, the congratulatory comments by both the FDA and Medtronic have covered up the serious problems of the failure of an earlier recall and the FDA's failure to stop Medtronic's outrageous and irresponsible Medtronic direct-to-consumer ad campaign.

We look forward to a prompt response to these serious problems.

72. By letter dated October 22, 2007, the Honorable Henry A. Waxman, on behalf of the House Committee on Oversight and Government Reform, requested information from the FDA commissioner in connection with the agency's approval of the Fidelis Leads.[8] Chairman Waxman requests for information sought, *inter alia*:

a. A chronology of FDA actions related to the approval of the Fidelis Leads;

b. A description of when and how the FDA "first became aware of the potential fracture problem and when [it] proposed that action be taken on this problem to the [C]ompany", as well as "the events leading to the voluntary recall [and] any communications FDA had with the [C]ompany regarding the recall";

c. Whether Medtronic's submission of adverse event reports to the FDA since the introduction of the Fidelis Leads to market submitted in a timely manner; and

d. Whether, "[i]n the aftermath of the problems found with the Guidant implantable defibrillators, did the agency create any guidances or policies for the oversight of these critical devices."

**BREACH OF FIDUCIARY DUTIES**

73. Each of the Defendants owed Medtronic and the Company's shareholders fiduciary duties of loyalty, good faith and due care in the context of exercising sufficient oversight and implementing and executing internal controls designed to ensure that the Company's products were safe and to ensure that management was not engaging in conduct that either jeopardized the public's health or the Company.

[8] Letter from Henry A. Waxman, Chairman, Committee on Oversight and Government Reform, United States House of Representatives, to Andrew C. von Eschenbach, M.D., Commissioner, FDA, (Oct. 22, 2007) <http://oversight.house.gov/documents/20071022181623.pdf>.

74. Each of the Defendants were and are required to act in the best interests of Medtronic and the Company's shareholders, and not in furtherance of their own personal interests.

75. Each of the Defendants owes to Medtronic and the Company's shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company's affairs, the use and preservation of its property and assets and the highest obligations of fair dealing.

76. Each of the Defendants had a duty to ensure that management promptly issue accurate and truthful information with regard to the safety profiles of the Company's products.

77. Defendants, directly and/or indirectly, engaged in reckless and wrongful acts complained of herein, including the failure to monitor and prevent, supervise and/or correct the dissemination of false and misleading information in the various public statements issued by the Company regarding the efficacy and safety of the Fidelis Leads.

78. To discharge their duties, Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the financial affairs of the Company. By virtue of such duties, the Director Defendants were required to, among other things:

a. Ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;

b. Conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets;

c. Properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results and prospects, and ensuring that the Company maintained an adequate system of controls such that the Company's financial reporting would be true and accurate at all times;

d. Remain informed as to how Medtronic conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

e. Ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.

79. Each of the Defendants, by virtue of his or her position as directors and/or officers of the Company, owed to Medtronic and the Company's shareholders the fiduciary duties of loyalty, good faith and the exercise of due care in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets.

80. The conduct of the Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Medtronic, the absence of good faith, and a reckless disregard for their duties to Medtronic and the Company's shareholders that each of the Director Defendants were aware or should have been aware posed a risk of serious injury to the Company.

81. The conduct of the Defendants who were also officers and/or directors of Medtronic during the Relevant Period have been ratified by the remaining Defendants who

collectively comprised all of the Company's Board of Directors during the Relevant Time Period.

82. The Defendants breached their duties of loyalty and good faith by causing, directly or indirectly, the Company to materially misrepresent the efficacy of the Fidelis Leads, its financial results and prospects, and by subjecting the Company to massive litigation exposures and reputational harm.

**CONSPIRACY, AIDING AND ABETTING AND CONCERTED ACTION**

83. In committing the wrongful acts alleged herein, each of the Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, each of the Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

84. During the Relevant Time Period, Defendants collectively and individually initiated a course of conduct that was designed to: (i) conceal the fact that the Company was improperly misrepresenting the safety and efficacy of its products; (ii) sell over $27 million of their personally held shares; and (iii) deceive the investing public, including the Company's shareholders, regarding their management of the Company's operations, financial health and stability, as well as its future business prospects. In furtherance of this plan, conspiracy and course of conduct, Defendants collectively and individually took the actions set forth herein.

85. During the Relevant Time Period, Defendants caused the Company to conceal the true fact that Medtronic was misrepresenting the safety and market acceptance of the Fidelis Leads. The purpose and effect of Defendants' conspiracy was, among other things, to disguise their breaches of fiduciary duty, waste of corporate assets and unjust enrichment, as well as to

conceal adverse information concerning the Company's business operations and future prospects.

86. Defendants accomplished their conspiracy, common enterprise and/or common course of conduct by causing the Company to purposefully, recklessly or negligently release improper statements. Because the actions described herein occurred under the authority of the Board of Directors, each of the Defendants was a direct, necessary and substantial participant in the conspiracy, common enterprise and/or common course of conduct complained of herein.

87. Each of the Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his overall contribution to and furtherance of the wrongdoing.

## IMPROPER INSIDE SELLING

88. The Defendants Collins and Hawkins, because of their respective positions, knew that, during the Relevant Time Period, the public statements by Medtronic were incorrect. They also knew and understood that the misstatements would create an inflated stock price for Medtronic Stock. Defendants Collins and Hawkins took advantage of this undisclosed information to sell their personally held Medtronic Stock for considerably more than it was worth.

89. While in possession of undisclosed material adverse information, Defendants Collins and Hawkins sold the following shares of Medtronic Stock:

| Inside Seller Name | Transaction Date | Shares | Price | Proceeds |
|---|---|---|---|---|
| Collins Jr., Arthur D. | 12/29/2006 | 7477 | $53.51 | $400,094.27 |
| | 12/29/2006 | 5225 | $53.51 | $279,589.75 |
| | 1/16/2007 | 1040 | $54.35 | $56,524.00 |

| | | | | |
|---|---|---|---|---|
| | 1/16/2007 | 2080 | $54.34 | $113,027.20 |
| | 1/16/2007 | 1040 | $54.31 | $56,482.40 |
| | 1/16/2007 | 1040 | $54.30 | $56,472.00 |
| | 1/16/2007 | 1040 | $54.28 | $56,451.20 |
| | 1/16/2007 | 2086 | $54.09 | $112,831.74 |
| | 1/16/2007 | 1040 | $53.95 | $56,108.00 |
| | 1/16/2007 | 1040 | $53.85 | $56,004.00 |
| | 6/6/2007 | 5877 | $52.55 | $308,836.35 |
| | 7/2/2007 | 120053 | $53.37 | $6,407,228.61 |
| | 7/2/2007 | 218843 | $53.37 | $11,679,650.91 |
| | 8/23/2007 | 38000 | $53.00 | $2,014,000.00 |
| | 9/17/2007 | 27671 | $54.21 | $1,500,044.91 |
| | 9/17/2007 | 17890 | $54.21 | $969,816.90 |
| | 9/17/2007 | 69566 | $21.56 | $1,499,982.09 |
| | 9/18/2007 | 24005 | $54.27 | $1,302,751.35 |
| | 10/23/2007 | 1138 | $48.03 | $54,658.14 |
| | 10/23/2007 | 1138 | $48.03 | $54,658.14 |
| | 10/26/2007 | 3 | $47.82 | $143.46 |
| **Collins Jr., Arthur D.** | | **547292** | | **$27,035,355.42** |
| Hawkins III, William A. | 4/17/2007 | 445 | $52.05 | $23,162.25 |
| | 6/6/2007 | 2743 | $52.55 | $144,144.65 |
| | 8/27/2007 | 728 | $53.69 | $39,086.32 |
| **Hawkins III, William A.** | | **3916** | | **$206,393.22** |

## DEMAND FUTILITY

90. Plaintiff has not demanded that the Company's Board of Directors bring the claims herein asserted because any such demand would be futile. Plaintiff is excused from making a demand for the reasons stated below.

91. This action is being pursued derivatively on behalf of Medtronic inasmuch as the Company's Board of Directors is grossly conflicted.

92. The Board of Directors cannot pursue a claim against the Director Defendants and the other Defendants since to do so would jeopardize the Company's directors and officers liability insurance coverage, which it is already being employed to defend the Company and its management, both former and current, in the pending securities class actions. Moreover, a pre-

suit litigation demand would be futile because it would demand that the Director Defendants sue themselves due to their lack of fidelity and care with respect to the oversight of the Company.

93. Moreover, as set forth above, the Company's Board of Directors was on prior notice that the Company was prone to regulatory scrutiny and that its products had been the subject to quality control issues, exposing Medtronic to massive litigation liabilities and reputational harm. Given this history, the Board of Directors should have undertaken corrective measures to address the problems arising with respect to the efficacy of the Fidelis Leads, at the very least, or to clarify the false statements issued to members of the medical community and their patients concerning the Leads.

94. The Directors of Medtronic consists of the following Defendants: Collins, Hawkins, Anderson, Calhoun, Jackson, Lenehan, O'Leary, Powell, Pozen, Rosso and Shuler.

95. Medtronic's Board of Directors, during the Relevant Time Period, failed to disclose the nature and extent of the Company's problems with its Fidelis Leads exposures. Additionally, Defendants Collins and Hawkins breached their fiduciary duties to Medtronic shareholders when they, upon information and belief, sold shares of personally held Medtronic Stock while in possession of material non-public information. Thus demand upon them is futile.

96. Defendants, O'Leary, Calhoun, Jackson, Pozen and Shuler are members of the Audit Committee and face a sufficiently substantial likelihood of liability for their breach of fiduciary duties attendant to their participation in the preparation of improper statements and earnings press releases that contained materially false and misleading financial information concerning the Company's business, revenues, and prospects. In particular, they were supine in the face of growing problems and failed to take corrective measures to address them or to clarify the false statements issued by Defendants concerning the Fidelis Leads. The Audit Committee's

members further failed to ensure that Medtronic fully disclosed all material information concerning the Company's problems with the Fidelis Leads, and that the Defendants' statements concerning the same were accurate. Indeed, the audit committee's charter explicitly states that members are tasked with ensuring that the Company comply with legal and regulatory requirements. Accordingly, the Audit Committee was duty bound to prevent management from issuing the March Dear Doctor Letter absent first conducting an investigation to ensure the veracity of the information in it.

97. The Company's Board has a Technology and Quality Committee. According to the Company, the committee is tasked with oversight responsibilities in the areas of safety and quality control and was the primary body responsible for the matter at issue here:

> Technology & Quality Committee Charter
>
> (As amended through June 23, 2005)
>
> The Technology and Quality Committee provides assistance to the board in its responsibilities concerning (a) the allocation of the corporation's resources to those scientific and technological efforts that offer the greatest potential growth to the corporation within the framework of the corporate objectives, (b) the adequacy and relevancy of the scientific and technical direction and the corporation's efforts, policies and practices in development and quality programs to meet the corporation's objectives and requirements for growth, and (c) evaluation of the processes in place for ensuring quality and safety of Medtronic products.
>
> The Technology & Quality Committee shall consist of at least three directors. The Committee, on behalf of the board, shall:
>
> review the processes in place to assure product quality and safety issues;
>
> at least two times a year, review the results of product quality assessments by Medtronic and external product quality audits by the FDA and various notified bodies;
>
> review management recommendations regarding product recalls or other significant product safety/quality issues;

> receive and review management's certification that its research operations are conducted in compliance with regulations governing good laboratory practices and standards for the ethical conduct of research involving animals or human subjects;
>
> review the results of and evaluate the effectiveness of the corporation's scientific and technological efforts and investments in developing new products and businesses;
>
> annually review progress on major scientific and technological programs; and
>
> evaluate the technological education, recognition and motivational programs and activities of the corporation.
>
> In addition, the T&Q Committee shall act as a channel of communications between the board and the chief quality officer in matters concerning the quality processes in the corporation. It shall report all committee activities and findings to the board with recommendations for action when appropriate.

98. Calhoun, Lenehan, Pozen and Powell serve on this committee. Not one is a medical doctor.

99. Demand on each of these directors would be futile because each suffers from the substantial threat of personal liability for their respective failures to ensure that management disseminated truthful and accurate information about the known problems associated with the Fidelis Leads. Moreover, they failed to either prevent or correct the patently misleading statements issued by the Company in connection with the March "Dear Doctor" letter, though they were tasked by charter to do so and given the Company's history of regulatory and safety problems and the existence of ample data that the leads were defective not failing because doctors inserted them incorrectly. Indeed, Dr. Hauser, a well-respected Minnesota doctor, performed a detailed study that yielded empirical data supporting an extremely strong inference that the Leads were both dangerous, lacked greater efficacy than older models that were not prone to safety concerns, and that physicians were not to blame for the problems. Given that this

information was available to the members of this committee, they were obligated by the committee's charter to take affirmative steps to investigate and remedy the problem.

**COUNT I**

**AGAINST ALL DEFENDANTS FOR BREACH OF FIDUCIARY DUTY**

100. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

101. Defendants owed and owe Medtronic fiduciary obligations. By reason of their fiduciary relationships, Defendants owed and owe Medtronic the highest obligation of good faith, fair dealing, loyalty and due care.

102. Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.

103. Defendants also each owed a duty to Medtronic to test, oversee and monitor their systems of internal controls, disclosure, financial and accounting controls, governance procedures and disclosures procedures with respect to the efficacy of the Fidelis Leads.

104. Each of the Defendants had actual or constructive knowledge of the problems with the Fidelis Leads and failed to take appropriate corrective and curative action. Each of their failures to act could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

105. As a direct and proximate result of Defendants' failure to perform their fiduciary obligations, Medtronic sustained significant damages. As a result of the misconduct alleged herein, the Defendants are liable to the Company.

106. As a result of the misconduct alleged herein, the Defendants are liable to the Company in an amount to be proven at trial.

**COUNT II**

**AGAINST ALL DEFENDANTS FOR ABUSE OF CONTROL**

107. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

108. Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Medtronic, for which they are legally responsible.

109. As a direct and proximate result of Defendants' abuse of control, Medtronic has sustained significant damages.

110. As a result of the misconduct alleged herein, Defendants are liable to the Company.

111. As a result of the misconduct alleged herein, the Defendants are liable to the Company in an amount to be proven at trial.

**COUNT III**

**AGAINST ALL DEFENDANTS FOR GROSS MISMANAGEMENT**

112. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

113. By their actions alleged herein, Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Medtronic in a manner consistent with the operations of a publicly held corporation.

114. As a direct and proximate result of the Defendants' gross mismanagement and breaches of duty alleged herein, Medtronic has sustained significant damages in excess of hundreds of millions of dollars.

115. As a result of the misconduct and breaches of duty alleged herein, the Defendants are liable to the Company.

116. As a result of the misconduct alleged herein, the Defendants are liable to the Company in an amount to be proven at trial.

**COUNT V**

**AGAINST INSIDE SELLING DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES FOR INSIDE SELLING AND MISAPPROPRIATION OF INFORMATION**

117. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

118. At the time of their stock sales, Defendant Collins and Hawkins knew the information described above and sold Medtronic Stock on the basis of such information.

119. The information described above was proprietary, non-public information concerning the Company's financial condition and future business prospects. It was a proprietary asset belonging to the Company, which Defendants Collins and Hawkins used for their own benefit when they sold Medtronic stock.

120. At the time of their stock sales, Defendants Collins and Hawkins knew that the Company faced a potential recall because the Leads suffered from undisclosed defects. Moreover, their sales of Medtronic Stock while in possession and control of this material adverse non-public information was a breach of their fiduciary duties of loyalty and good faith.

121. Since the use of the Company's proprietary information for their own gain constitutes a breach of Messrs. Collins' and Hawkins' fiduciary duties, the Company is entitled to the imposition of a constructive trust on any profits they obtained from the transaction.

**COUNT VI**

**AGAINST ALL DEFENDANTS FOR AIDING AND ABETTING BREACHES OF FIDUCIARY DUTY**

122. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

123. As described above, each of the Defendants aided and abetted one or more of the other Defendants in breaching fiduciary duties owed to Medtronic.

124. As a direct and proximate result of the Defendants' aiding and abetting breaches of fiduciary duty, Medtronic engaged in imprudent and unlawful activities which have caused the Company to suffer damages, as alleged herein.

**AS TO ALL COUNTS**

WHEREFORE, Plaintiff prays for judgment as follows:

a. Determining that his suit is a proper derivative action and certifying Plaintiff as appropriate representatives of Medtronic for said action;

b. Declaring that each of the Defendants breached his fiduciary duty to Medtronic;

c. Directing each of the Defendants to account to the Company for all damages sustained or to be sustained by the Company and all profits obtained by Defendants by reason of the wrongs alleged herein;

d. Requiring all Defendants to return to Medtronic all compensation paid to them during the Relevant Time Period;

e. Ordering Defendants, and those under their supervision and control, to implement and enforce policies, practices and procedures on behalf of Medtronic and

its stockholders that are designed to detect and prevent illegal conduct by the Company's employees and representatives;

f. Directing each of the Defendants to pay interest at the highest rate allowable by law on the amount of damages sustained by the Company and the selling Defendants' unlawful profits as a result of the culpable conduct of each of the Defendants;

g. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs and expenses; and

h. Granting such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

Dated: January 9, 2008

**REINHARDT, WENDORF & BLANCHFIELD**

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Attorneys for Plaintiffs

/497408

**VERIFICATION**

I, Iris Markewich, declare that I have reviewed the complaint ("Complaint") prepared on behalf of Medtronic, Inc., and I authorize its filing. I have reviewed the allegations made in the Complaint, and to those allegations to which I have personal knowledge, I believe those allegations to be true. As to those allegations to which I do not have personal knowledge, I rely on my counsel and their investigation and for that reason believe them to be true. I further declare that I am a current holder, and have been a holder, of common stock during the time period, in which the wrongful conduct alleged and complained of in the Complaint, occurred.

1/8/08
Date

Iris Markewich
IRIS MARKEWICH